Division of Behavioral Health Services

Project: Informed Consent for Psychotropic Medication Prescription

Performance Improvement Project (PIP)

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September 15, 2005

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I. EXECUTIVE SUMMARY

The Arizona Department of Health Services/Division of Behavioral Health Services (ADHS/DBHS) initiated the Performance Improvement Project "Informed Consent for Psychotropic Medication Prescription" in January 2003. ADHS/DBHS determined that this would involve a statewide project to improve the practice of obtaining and documenting informed consent for psychotropic medications prescribed to Title XIX/XXI persons enrolled in the state's behavioral health system. The first report, submitted to AHCCCS on December 15, 2003, established the groundwork for the project. This report covers activities from Years 2 and 3, encompassing December 2003 through August 2005.

The Informed Consent Workgroup is comprised of Regional Behavioral Health Authority (RBHA) and Provider Medical Directors or their designees, the ADHS/DBHS Medical Director, ADHS/DBHS Quality Management staff, ADHS/DBHS Policy Office staff, and a Consumer/Physician representative. The workgroup has utilized the I-M-P-R-O-V-E / P-D-C-A performance improvement model since the onset of the project. Significant accomplishments of the Workgroup include:

Year 1

- Standardized the "Informed Consent Format" for documenting informed consent. See Appendix A.
- Developed a detailed set of guidelines, "Informed Consent For Psychotropic Medication Treatment Technical Assistance Document" (I.C.F.P.M.T. TAD). See Appendix B.
- Began developing revised questions for the Independent Case Review (ICR) tool.

Years 2 and 3

- Disseminated the "Informed Consent For Psychotropic Medication Treatment TAD" and required its use statewide.
- Encouraged the statewide implementation of the "Informed Consent Format".
- Implemented revisions to the criteria to measure informed consent on the 2004 ICR tool.

Results of Informed Consent data obtained from ICR audits demonstrate significant progress was made toward improving compliance with informed consent requirements between the 2003 ICR and 2004 ICR. The 2003 ICR results demonstrated a statewide compliance rate of 53.3% for adults and 63.5% for children. The 2004 ICR results demonstrated an increase to 64.2% for adults and 68.9% for children of records containing consent for new psychotropic medications prescribed. This is a significant accomplishment given that for the 2003 ICR only 75% of medications had to have informed consent in comparison to 100% of medications for the 2004 ICR. The standard was raised and performance still improved.

Informed Consent is an area in need of improvement across all RBHAs and at a statewide level. The Informed Consent Workgroup will continue to meet quarterly to

review results from T/RBHA monitoring activities and discuss issues as they arise in the implementation and make recommendations for performance improvement.

II. Introduction

The prescription and provision of psychotropic medications is an integral part of the overall treatment of behavioral health consumers. The purpose of requiring informed consent is to promote autonomy of the individual in medical decision making (Hartman,R.: A Concept Analysis of Informed Consent). Informed consent ensures that patients are aware of and fully understand all treatment options, and the risks and benefits associated with them. Autonomy allows patients to voice opinions about those health care options (Maynard, S.: "Informed Consent"). Consumers have the right and responsibility to fully participate in all decisions related to their health care. Greater individual involvement by consumers in their care increases the likelihood of achieving the best outcomes and helps support a quality improvement, cost-conscious environment (Advisory Commission on Consumer Protection and Quality in the Health Care Industry).

Informed consent creates a supportive atmosphere, provides necessary information and empowers the consumer by making him/her an active partner and participant in the decision making process. Research related to noncompliance with medications has shown a relationship between medication compliance and information provided to the consumer (Rana & Ayub, 2002; State of Ohio Department of Mental Health, 1997).

Informed Consent Definition

In accordance with the ADHS/DBHS Provider Manual Section 3.15, "Psychotropic Medication: Prescribing And Monitoring", complete informed consent includes discussion and documentation of the following elements in a manner that the person/legal guardian can understand:

- The diagnosis and target symptoms for the medication being prescribed;
- The benefits/intended outcome of treatment, and the risks and side effects of each medication;
- Alternatives to the proposed medication treatment;
- The possible results of not taking the recommended medication;
- The possibility that medication dosages may need to be adjusted over time, in consultation with the medical practitioner;
- The person's right to actively participate in treatment by discussing medication concerns or questions with the medical practitioner; and
- The person's right to withdraw voluntary consent for medications at any time (unless the medication(s) in the treatment plan are required in a Court Order or in a Special Treatment Plan).

Project Goal

The goal of this project is to improve the practice of obtaining and documenting informed consent from persons/legal guardians for all prescribed psychotropic medications. ADHS/DBHS has established a minimum performance standard of 80% compliance as indicated in the AHCCCS/ADHS contract.

Possible Causes/Barriers

The following possible barriers were identified by the Workgroup during Year 1 of this performance improvement project: Consumer and Cultural Competence, Prescribing Clinician Capacity, Legal Issues, and Broad Systems Issues. The Workgroup discussed possible solutions to these problems and developed a Plan of Action.

Additionally, in Years 2 and 3 of this project, the following possible barriers were explored:

- Resistance from doctors
- Anti-psychotic medication liability issues
- Training and compliance with use of the form by part-time providers
- The need to reinforce the practice of obtaining Informed Consent
- Strain on provider capacity
- The use of electronic medical records versus paper records

The workgroup discussed the following solutions to the identified barriers:

- Design charts so relevant sections are easy to access
- Reinforce the practice of obtaining Informed Consent
- Include the Informed Consent format with doctors orders
- Include the Informed Consent format as part of the prescribing clinician's package for assessment or appointments
- Provide training and technical assistance to those providers out of compliance
- Targeted interventions and corrective actions for individual providers

III. Methodology

This project monitors the implementation of obtaining and documenting informed consent for prescribing psychotropic medications as it applies to Title XIX/XXI adults and children. The project utilizes Independent Case Review (ICR) data to determine the rate at which adequate informed consent is obtained from the person/legal guardian for all new psychotropic medications prescribed.

Sample

Based on statewide enrollment numbers, proportional samples of children and adults were drawn for each Geographic Service Area (GSA). This generated a total GSA sample size. The sample size assured a minimum error rate of 5 percent and 90 percent confidence level for each GSA.

Performance Indicators

For the 2004 ICR, the following performance indicators were utilized to measure the progress of this project:

1) **Percent of individuals and/or parents/guardians who are informed and give consent for all of the new psychotropic medications prescribed during the review period.**

Numerator: Number of cases that scored 'Yes' to the following ICR item: *"Individuals and/or parent/guardians are informed and give consent for all of the new psychotropic medication prescribed during the review period"*
Denominator: Total number of sample cases for this project

2) Percent of cases containing informed consent for prescribed medication with documentation that includes all of the components listed below:

- **Benefits/intended outcome of treatment**
- **Individual's Risk and side effects**
- **Possible alternatives to the proposed medication**
- **Possible results of not taking the recommended medication**
- **The person's right to withdraw voluntary consent for medication at any time**

Numerator: Number of informed consents that include each of the five components of informed consent
Denominator: Total number of sample cases for this project

This project observes the AHCCCS/ADHS contract standards, as follows:
Minimum: 80%
Goal: 90%
Benchmark: 95%

IV. DATA ANALYSIS

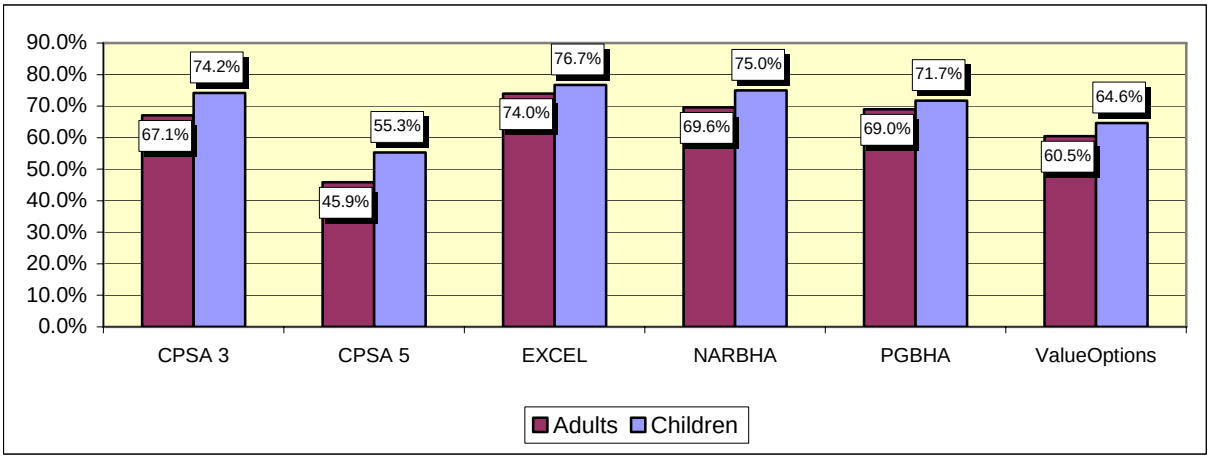
The following are the results for the two key indicators measured in the 2004 ICR, Questions 15a and 15b:

1. **Individuals and/or parents/guardians are informed and give consent for all of the new psychotropic medications prescribed during the review period.**

A. Statewide performance:

ICR Standard	**Minimum Performance Score**	**Statewide Results**	
		Adults	**Children**
Individuals and/or parent/guardians are informed and give consent for all of the psychotropic medications prescribed during the review period.	**80%**	**64.2%**	**68.9%**

B. RBHA performance:



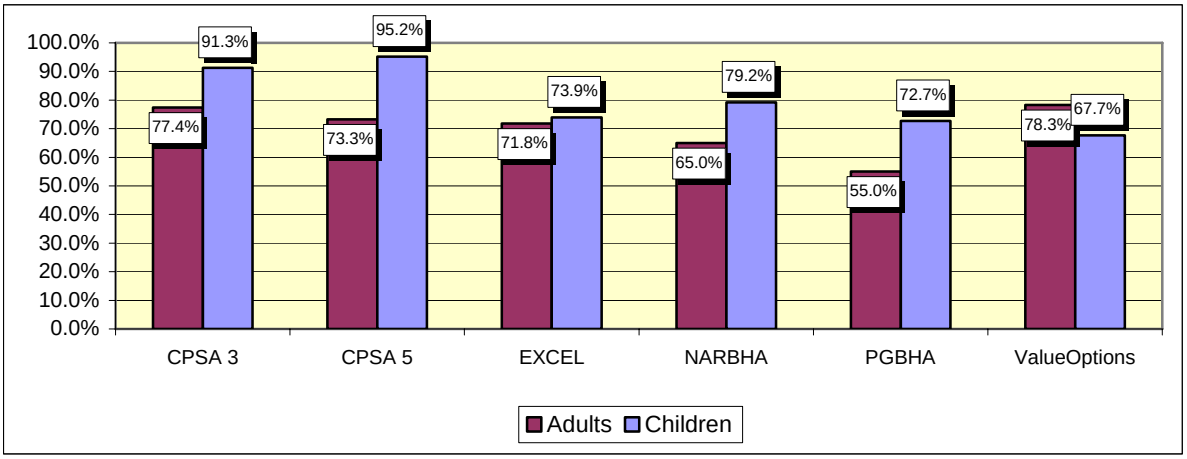
Statewide performance did not meet the minimum performance score of 80% for either the Adult or the Child population. For the Adult population, overall scores ranged from a low of 45.9% for CPSA 5 to 74.0% for PGBHA. For the Child population, overall scores ranged from a low of 55.3% for CPSA 5 to 76.7% for PGBHA.

2. **For all of the new psychotropic medications prescribed during the review period from "15a", informed consent documentation includes all of components:**

A. Statewide performance:

ICR Standard	Minimum Performance Score	Statewide Performance	
		Adults	Children
For all of the new psychotropic medications prescribed during the review period from "a" informed consent documentation includes the following:	80%	69.8%	78.7%
Benefits/intended outcome of treatment		91.8%	95.5%
Individual's Risk and side effects		87.3%	93.5%
Possible alternatives to the proposed medication		73.3%	81.3%
Possible results of not taking the recommended medication		71.4%	80.6%
The person's right to withdraw voluntary consent for medication at any time		70.6%	78.7%

B. RBHA performance.



The minimum performance score of 80% was not met for either the Adult or Child populations, although the Child score was close at 78.7%. For the Adult population, overall performance scores ranged from a low of 55% for PGBHA to 78.3% for ValueOptions. For the adult population, the components most often missed were:

- Possible alternatives to the proposed medication
- Possible results of not taking the recommended medication
- The person's right to withdraw voluntary consent for medication at any time

For the Child population, overall performance scores ranged from a low of 67.7% for ValueOptions to a high of 95.2% for CPSA 5. For the child population, the component most often missed was:

- The person's right to withdraw voluntary consent for medication at any time

Limitations of Data

It is important to note that a direct comparison of results from the Informed Consent standard for the 2002, 2003, and 2004 ICRs is not possible because the standard was revised for each of the years subsequent to 2002. The following is the methodology used for this standard for each year:

2002 ICR:
"Individuals and/or parent/guardians are informed about and give consent for prescribed medications."

2003 ICR:
"Individuals and/or parent/guardians are informed and give consent:
a.) for **at least 75%** of new psychotropic medication prescribed during the review period
b.) for **at least 75%** of new psychotropic medication from "a" with an informed consent, documentation includes all of the following: 1) Benefits/intended outcome of treatment; 2) Individual's risk and side effects; 3) Possible alternatives to the proposed medication; 4) Possible results of not taking the recommended medication; 5) The person's right to withdraw voluntary consent for medication at any time."

2004 ICR:
"Individuals and/or parent/guardians are informed and give consent:
a.) for **all** of the new psychotropic medications prescribed during the review period
b.) for **all** of the new psychotropic medications from "a" with an informed consent, documentation includes all of the following: 1) Benefits/intended outcome of treatment; 2) Individual's risk and side effects; 3) Possible alternatives to the proposed medication; 4) Possible results of not taking the recommended medication; 5) The person's right to withdraw voluntary consent for medication at any time."

The 2004 ICR was similar to the 2003 ICR question except "**75%**" was replaced with "**all**".

V. DISCUSSION

Although assumptions based on comparison between the results from the 2003 ICR and 2004 ICR are limited, there is evidence of progress being made toward the achievement of the 80% minimum performance score.

- The 2003 ICR results showed only 53.3% and 63.5% of the adult and child populations respectively were informed regarding newly prescribed psychotropic medications for a minimum of **75%** of the medications prescribed.
- The 2004 ICR results showed 64.2% and 68.9% of the adult and child populations respectively were informed regarding newly prescribed psychotropic medications for a minimum of **100%** of the medications prescribed.

This is a significant accomplishment given that for the 2003 ICR only 75% of medications had to have informed consent in comparison to all medications for the 2004 ICR. The standard was raised and performance still improved.

VI. CONCLUSION

Informed Consent is an area in need of improvement across all RBHAs and at a statewide level. The Informed Consent Workgroup will continue to meet quarterly to review results from T/RBHA monitoring activities, discuss issues as they arise, and make recommendations for performance improvement. The Workgroup will continue with monitoring activities such as chart reviews to identify prescribers who did not comply with informed consent performance standards. The Workgroup will also explore the possibility of measuring the adequacy of informed consent from the consumer's perspective.

Data collected during the 2004 ICR indicated only 68.3% of adult charts and 79.4% of child charts contained the new standardized consent form for all newly prescribed psychotropic medications. This data will be analyzed to assess what impact use of the new forms had on the overall improved performance scores. In addition, many charts did not include all of the required information components relating to informed consent. Focus in these areas will be included in future efforts of the workgroup. It is believed that appropriate use of the format will ensure that when psychotropic medications are prescribed to enrolled clients, they will be provided a quality process allowing them to

make informed decisions regarding the use of psychotropic medications as a part of their treatment. The Workgroup will utilize information from the 2004 ICR to identify and address barriers related to implementation of the standardized Informed Consent format.

Appendix A. Informed Consent For Psychotropic Medication Treatment Format (Last Revision 8/1/2004)

Appendix B. Informed Consent For Psychotropic Medication Treatment: Technical Assistance Document (Last Revision 1/15/2004)